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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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07/24/2006

Sergey Bujanover

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23405

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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT

PAPER NUMBER

1648

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,599	Applicant(s) BUJANOVER, SERGEY	
	Examiner BENJAMIN P. BLUMEL	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 44-49, 51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 44-49, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1648

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

Claims 1-19, 44-49, 51 and 52 are examined on the merits.

Response to Arguments

Applicant's arguments filed April 24, 2008 have been fully considered but they are not persuasive. See responses below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(Prior Rejection Maintained) Claims 1-19, 44-49, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanstrom and Adams (Proceedings of the Society for Exp. Biology and Medicine, 1951), Takahashi et al. (US Pat. 6,322,783 B1), Pelletier et al. (US PGPub 2004/0091856 A1) and Agrawal (US Pat. 6,482,632 B2).

Applicants argue that the method disclosed by Swanstorm, as well as slightly modified methods, have long been used on a laboratory scale. Particularly, these methods are suitable for the growth and isolation of a specific bacteriophage type or a mutant. Such methods are also used by Takahashi and by Pelletier. However, when multiplication of bacteriophages is required, even at a small laboratory scale, liquid cultures are preferred, as disclosed, for example, by

Art Unit: 1648

Takahashi (column 17, line 41). Thus, the combination of references teaches away from the claimed invention, which uses a two layer, solid phase/semi-solid phase system. Up to the time of the present invention, based on the laboratory experience, attempts for scaling up bacteriophage growth were directed toward culture production, which requires the use of very large fermenters that are difficult and expensive to operate. This is based in part on the fact that the semi-solid layer disclosed by Swanstorm contains agar at a concentration of about 0.7%. Thus, scraping this layer from the bottom layer to enable bacteriophage isolation is not highly efficient. Compare for example 36 ml yield of crude phage extract in Swanstorm (see Swanstorm at page 372, col. 2) with 55 liters of crude phage extract in the present invention (see Fig. 2A of application).

In response, even though Swanstrom et al. only use a two-layer agar method of producing bacteriophage on a small scale and since large quantities of bacteriophage are produced primarily through liquid fermenters, this is not considered to teach away from increasing the system taught by Swanstrom et al. because, the MPEP states at section 2124 (II):

[Disclosed examples and preferred embodiments **do not constitute a teaching away from a broader disclosure or nonpreferred embodiments.** *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (**The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material.** The applied prior art reference taught a printed circuit material similar to that of the claims **but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use,** but that epoxy impregnated circuit boards have “relatively acceptable dimensional stability” and “some degree of flexibility,” **but are inferior to circuit boards impregnated with polyester-imide resins.** The court upheld the rejection concluding that applicant’s argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since “Gurley asserted no discovery beyond what was known in the art.” 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, “[t]he prior art’s mere disclosure of more than one alternative].

Applicants also argue that the present invention is based in part on the unexpected finding that reducing the hydrocolloid (e.g. agar) concentration in the top layer not only significantly enhances the efficacy of bacteriophage extraction, but also results in a high bacteriophage titer of at least 10^{11} typically of 10^{15} to 10^{16} . Such yield increase would not have been obvious to a person skilled in the art at the time of the invention. As it is understood from the context of the disclosure of Agrawal, and as is acknowledged by the Examiner, Agrawal at most suggests that using agar concentration of 0.3% does not affect the phage production. Nowhere in Agrawal is it disclosed or suggested that reducing the top-layer agar concentration would result in an increased bacteriophage titer.

In response, even though applicants state that by reducing the bacteriophage extraction efficiency by lowering the agar concentration, such data substantiating this claim has not been provided. It is suggested that information showing that a semi-solid layer with a less than 0.5% agar or 0.3% agar does yield higher titers as compared to 0.5% or slightly higher concentrations would aid in determining these unexpected results.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(New Rejection) Claims 1-19, 44-49, 51 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: “wherein the semi-solid culture medium is supported by a solid phase” in claim 1. Claims 2-19, 44-49, 51 and 52 are rejected since they depend from claim 1.

Art Unit: 1648

Claim Objections

(New Objection) Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 recites, "The method according to claim 10, wherein the semi-solid culture medium is layered on top of a first supportive solid phase bottom layer to form a second top layer", however, claim 10 recites, "...the semi-solid culture medium is supported by a solid phase". Therefore, claim 11 does not further limit claim 10 since it too states that a solid support layer is formed underneath that of the semi-solid layer.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648